

**REMARKS**

In response to the final Official Action of August 31, 2010 and Advisory Action of November 24, 2010, claims 1, 3 and 4 have been amended.

Claim 1 has been amended to recite “the closure is provided with a frangible portion for the release of the counter, such that the closure is tamper-evident.” Support for this amendment can be found in previously presented claims 3 and 4, and the filed application (WO 2005/056090) at page 4, lines 4-16 and page 9, line 19-page 10, line 25.

**Claim Rejections - 35 USC §103**

At pages 2-4 of the Final Office Action, claims 1,3, 4, 7-11, 15, 16, 19, 20, and 23-25 are rejected under 35 USC §103(a) as unpatentable over U.S. Patent 5,020,527, Dessertine, in view of WO 01/37909, Höerlins.

With respect to claim 1, the Office asserts that Dessertine discloses a dispenser for dispensing a substance in individual portions counted by a multi-use counter having a display incremented or decremented with the count portions dispensed and a dispense action detector for detection of the portion dispensing, with the dispenser comprising a body having a dispensing orifice, as well as a container for the substance, the container being integral with or accompanied on the body, a mechanism in the body and/or the container for dispensing individual portions of the substance to the orifice, the mechanism having a displaceable element for initiating the dispensing action, and an accommodation on the body for the counter with its detector arranged for detection of dispensing action of the mechanism. Reliance is placed on Figures 1 and 4 of Dessertine and associated elements set forth by the Office on pages 2-3 of the Action.

Höerlins is cited as disclosing a dispenser wherein the closure is adapted to co-operate with a portion of the body providing the accommodation for removably enclosing the counter in the accommodation, characterized in that the closure is tamper evident, with the assertion that it would be obvious to one of ordinary skill in the art at the time the invention was made to have modified the teaching of Dessertine to have included a closure cap adapted to enclose the counter to the body of the apparatus such that the removal of the closure cap would be tamper evident if removed from the dispenser as taught by Höerlins because enclosing the counter would prevent accidental activation

of the counter and also alert a user if the closure is removed from the apparatus, and thus, the cap is tamper evident if removed. Applicant respectfully disagrees.

Applicant has amended claim 1 to recite the dispenser comprises “a closure adapted to co-operate with a portion of the body providing the accommodation for removably enclosing the counter in the accommodation, characterised in that the closure is provided with a frangible portion for the release of the counter, such that the closure is tamper-evident.” Thus, as amended, it is clear that in claim 1 the “tamper-evident” feature of the claimed invention is achieved by the closure being provided with a frangible portion for release of the counter. In the claimed invention, once the counter is removed from the closure, the frangible portion of the closure is broken and the user is immediately aware that the closure has been tampered with. Therefore, following the suggestion of the Office, Applicant respectfully submits that it is in clear in claim 1 as amended how the closure is tamper-evident (See Advisory Action, page 2, lines 7-8).

It is described in further detail in Applicant’s specification and drawings, how the frangible portion results in the closure being tamper-evident. For example, Figures 1-4 (described at page 9, line 19-page 10, line 25) show an embodiment of the invention in which the closure (cap 11) with a removable end disc (23). The central portion (32) of the end disc is frangible with a tear groove (26) (Application as filed, page 9, lines 28-32). Once the dispenser is exhausted, the end disc is severed from the rest of the closure and the counter is removed and the cap cannot be reused (Application as filed, page 9, lines 15-21). Thus, the frangible portion of the closure (i.e., tear groove 26) provides evidence that the closure has been tampered with. Consequently, a user cannot accidentally fit a counter to a partially or totally used dispenser without being aware that the counter will show an inaccurate number of doses.

Although Applicant maintains that the cited references do not disclose or suggest the tamper-evident feature of the claims as they were previously presented for the reasons set forth in the Request for Reconsideration filed on October 29, 2010, Applicant respectfully submits that the cited references, Dessertine and Höerlins do not disclose or suggest the feature of amended claim 1 of “a closure adapted to co-operate with a portion of the body providing the accommodation for removably enclosing the counter in the accommodation, characterised in that the closure is

provided with a frangible portion for the release of the counter, such that the closure is tamper-evident.”

Dessertine discloses a dispenser having a resettable counter and timer unit for monitoring the number of spray doses dispensed by an inhaler. The unit (21) shown in Figure 4 includes an automatic counter chip with a long-life miniature battery which is activated by downward movement of the container (15) against a lever (23) connected to the unit (21). The action of the lever on the unit simultaneously activates the timer which then signals a “beep” sixty seconds after the lever (23) has been depressed. Once a user has finished, the unit (21) may be simultaneously stopped and reset by depressing the reset button (29). As acknowledged by the Office in the Final Office Action, Dessertine does not disclose a closure adapted to enclose a counter and does not disclose a closure which is tamper-evident. Therefore, Dessertine does not disclose or suggest the feature of amended claim 1.

Höerlins discloses a counting mechanism (2) for counting the number of spray doses dispensed by an inhaler. The counting mechanism comprises a cap (7), a counting wheel (8) and a control wheel (9) and is mounted on the body of an inhaler as shown in Figure 1. The mounting of the counting mechanism on the inhaler is via an arrangement shown in Figures 2b and 6 and described at page 12 of the description. Essentially, the inhaler body is provided with flanges (40, 45) and the cap with an edge (13) and flanges (15) that co-operate therewith. Thus, the counting mechanism is fitted with the cap (7) tight over the flange of the coupling arrangement.

Höerlins does not, however, disclose a closure provided with a frangible portion for the release of the counter, such that the closure is tamper-evident, as required by amended claim 1. Rather, the cap (7) of Höerlins can be removed and replaced freely and repeatedly and there is no disclosure or suggestion that the cap has a frangible portion for the release of the counter such that the closure is tamper evident. The cap in Höerlins is described at page 2, lines 13-20 and at page 8, lines 29-page 9, line 16. The cap has an outer surface, an inner surface, a flange-like cap edge 13, a gear ring 11, an indicator window 10 and two concentrically arranged inner flanges 15, 17 (See also Figures 2a and 2b). It is clear from the description of the cap in Höerlins that it

does not comprise any feature that could be considered a frangible portion for release of the counter.

Therefore, the counting mechanism of Höerlins comprising the cap (7) could easily be removed from a first dispenser and put onto a second partially used dispenser without any indication to the user that the closure had been tampered with. The user of the dispenser would therefore not know, or may forget, that the counter is inaccurate and therefore is at risk of not replacing the medicament source present in their dispenser at the appropriate time.

Because neither Dessertine nor Höerlins disclose or suggest the user of a tamper-evident closure as defined by amended claim 1, it is respectfully submitted that the claimed invention is not obvious in view of these two references, as even if they were combined by a person having ordinary skill in the art, it still would fail to disclose the feature of amended claim 1.

Furthermore, it is respectfully submitted that a person having ordinary skill in the art reading Höerlins would not be motivated to incorporate its cap into the device of Dessertine. There are key functional differences between the dispensers of Dessertine and Höerlins that would lead the skilled man away from combining their teachings.

Dessertine is directed to inhalers with a built-in counting means and timing means (49) (Dessertine, column 2, lines 41-42). Figure 4 of Dessertine, described at column 3, lines 40 *et seq.*, shows the details of the counting and timing unit (49). It has a curved back (51) for attachment to the inhaler by known plastic-to-plastic means or other known assembly means. The unit is also described as being detachable and usable with many inhalers adapted to have the unit removably attached thereto (Dessertine, column 3, lines 50-52).

In contrast, the counting mechanism of Höerlins is mounted on the inhaler by a coupling arrangement between the cap (7) and the inhaler shown in Figure 6. The cap (7) of Höerlins is therefore a functional part of the coupling arrangement of the counting mechanism to the inhaler. The counting mechanism relies on the cap (7) for it to be mounted on the dispenser body. This is completely distinct from the attachment of the unit in Dessertine. Thus, a person of ordinary skill in the art would not be able to incorporate the cap of Höerlins into the device of Dessertine without significantly modifying the attachment of Dessertine's counting and timing means.

Moreover, the counting means of Dessertine is reliant on an electronic counter activated by the downward movement of the canister against a lever which activates the automatic counter chip therein (Dessertine, column 3, lines 1-8). In contrast, the counting mechanism of Höerlins, shown in Figure 7, relies on a gearing mechanism and rotation of a control wheel (9) and a counting wheel (8). Thus, the counting mechanisms of these two documents are also completely different.

Furthermore the cap (7) in Höerlins is also a functional part of its counting mechanism. This is evidenced by the fact that it carries teeth on its interior (see Figure 2b). These teeth ensure that the counting wheel rotate by the correct amount and that the correct dose is displayed through the indicator window of the cap. The person of ordinary skill in the art reading Höerlins would therefore not be motivated to incorporate its cap into Dessertine, as it is not possible to incorporate the cap with teeth on its interior into its electronic counting mechanism. The teeth of the cap would serve no purpose in the electronic counting mechanism of Dessertine.

The person of ordinary skill in the art therefore has no motivation to combine the teachings of Dessertine with Höerlins. These two documents teach completely different coupling arrangements between the counting means and the dispenser body, completely different counting mechanisms and the cap (7) is a functional part of both the coupling arrangement and the counting mechanism of Höerlins. Therefore, it would not have been obvious to a person of ordinary skill in the art to modify the device of Dessertine in order to incorporate the cap (7) taught in Höerlins.

It is therefore respectfully submitted that claim 1 as amended is distinguished over Dessertine in view of Höerlins.

Dependent claims 3, 4, 7-11, 15, 16, 19, 20, and 23-25 are also believed to be distinguished over Dessertine in view of Höerlins at least in view of their ultimate dependency from amended claim 1.

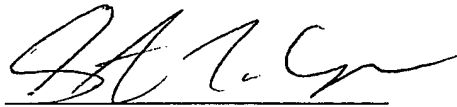
Finally, dependent claims 32-34 should also be rejoined in view of the arguments in support of allowability of claim 1 from which these claims ultimately depend.

In view of the foregoing, it is respectfully submitted that the present application as amended is in condition for allowance and such action is earnestly solicited.

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The Commissioner is hereby authorized to charge to deposit account 23-0442 any fee deficiency required to submit this paper.

Respectfully submitted,



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